REMARKS

Claims 1, 3, 12 and 21 have been amended.

Claim 9 has been canceled.

35 U.S.C. §103

MPEP 706.02(j) states:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 1438 (Fed. Cir. 1991) (emphasis added).

Claims 1-2, 9

Amended claim 1 claims "[a]n integrated anastomosis tool for forming an opening in a target vessel and connecting a graft vessel to the target vessel, the device comprising: a substantially hollow chamber and an introducer positioned at a distal end of the chamber and having a lumen open to the chamber, the introducer configured to substantially seal against the target vessel, whereby the chamber substantially maintains hemostasis; a cutting device movably attached to the tool body and configured to form the opening in the target vessel; and a graft vessel attachment device movably attached to the tool body and configured to connect the graft vessel to the target vessel; wherein the cutting device is movable both longitudinally and transversely, and wherein the cutting device is movable to a position within the chamber, and remains at a position within the chamber, after forming the opening in the target vessel."

Claim 1 requires a chamber that substantially maintains hemostasis, and requires the cutting device to be "movable to a position within the chamber, and remain[] at a position within the chamber, after forming the opening in the target vessel." (*e.g.*, paragraph 0049; Figures 5-6). First, turning to U.S. Pat. No. 6,605,098 to Nobis et. al. ("Nobis"), the Office Action implies that the compartment within which the cartridge 200 and punch assembly 600 may be placed is analogous to the claimed "chamber[that] substantially maintains hemostasis." However, that volume of the tool of Nobis is open, such that it does not and cannot maintain hemostasis. (Nobis; *e.g.*, Figure 1). Thus, Nobis neither teaches nor suggests the claimed "chamber [that] substantially maintains hemostasis."

Second, to allow the cartridge 200 to be placed in that compartment, the punch assembly 600 is moved out of that compartment after cutting a hole in the target vessel. (Nobis; *e.g.*, Figures 13, 14a). Thus, the punch assembly 600 does not remain at a position within the chamber after forming the opening in the target vessel, as required by claim 1. Turning to Figure 18, Nobis discloses a small sealed area distal to the elastomer sheet 633, near the distal end of the tool. (Nobis; col. 9, lines 36-43; Figure 18). However, the punch assembly 600 does not remain at a position within that area after forming the opening in the target vessel; indeed, the punch assembly 600 cannot remain within that area, because the punch assembly 600 would block the advancement of the cartridge 200 if the punch assembly remained in that area. (Nobis; col. 9, lines 39-43; Figures 15a-15b, 18). Turning to U.S. Pat. No. 6,672,088 to Vargas et. al. ("Vargas"), that patent also does not disclose the claimed "chamber [that] substantially maintains hemostasis."

Thus, the combination of Nobis and Vargas does not and cannot teach or suggest all of the limitations of amended claim 1. Consequently, claim 1 is believed to be in condition for allowance. Because claims 2 and 9 depend from amended claim 1, which is believed to be in

condition for allowance, claims 2 and 9 are believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 3-8

Claim 3 has been amended to claim "[a] device for forming an opening in a target vessel and delivering an implantable anastomosis device to connect a graft vessel to the target vessel, the device comprising: a tool body having a lumen; a cutting device configured to form the opening in the target vessel, the cutting device being movable at least partially within the lumen, and the cutting device defining a longitudinal axis when the cutting device is positioned to form the opening in the target vessel; and a graft vessel attachment device movable at least partially within the lumen for delivering the implantable anastomosis device to the target vessel to connect the graft vessel to the target vessel; wherein the cutting device is movable both longitudinally along and away from the longitudinal axis after forming the opening in the target vessel."

In contrast, U.S. Patent Application Publication No. 2002/0173808 of Houser et. al. ("Houser") discloses a tool in which a cutter moves solely longitudinally along its own longitudinal axis. (Houser; paragraph 0126; Figures 21a-22). Houser does not teach or suggest a cutting device that is movable "away from the longitudinal axis," whether before or after forming the opening in the target vessel; instead, Houser is directed only to "advancing" and "retracting" a cutter. (Houser; paragraph 0126). Thus, Houser neither teaches nor suggests the claimed "cutting device defining a longitudinal axis when the cutting device is positioned to form the opening in the target vessel… wherein the cutting device is movable both longitudinally along and away from the longitudinal axis after forming the opening in the target vessel." (emphasis added). As a result, claim 3 is believed to be in condition for allowance. Because

claims 4-8 depend from amended claim 1, which is believed to be in condition for allowance, claims 4-8 are believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 12-14

Amended claim 12 claims "[a] device for forming an opening in a target vessel, delivering an implantable anastomosis device to the target vessel, and connecting a graft vessel to the target vessel, the device comprising: a substantially hollow chamber and an introducer positioned at a distal end of the chamber and having a lumen open to the chamber, the introducer configured to substantially seal against the target vessel, whereby the chamber substantially maintains hemostasis; a cutting device configured to form the opening in the target vessel; and a graft vessel attachment device configured to deliver and deploy the implantable anastomosis device to connect the graft vessel and the target vessel; wherein the cutting device and the graft vessel attachment device are mechanically linked to sequentially pass the cutting device and the graft vessel attachment device through a particular point in proximity to an anastomosis site and wherein the cutting device moves to a position within the chamber, and remains at a position within the chamber, after forming the opening in the target vessel."

The discussion above with regard to claim 1 applies equally here. The combination of Nobis and Vargas does not teach or suggest the claimed "chamber [that] substantially maintains hemostasis," or the "cutting device [that] moves to a position within the chamber, and remains at a position within the chamber, after forming the opening in the target vessel." Because the combination of Nobis and Vargas does not teach or suggest all of the limitations of amended claim 12, claim 12 is believed to be in condition for allowance. Because claims 13-14 depend from amended claim 12, which is believed to be in condition for allowance, claims 13-14 are believed to be in condition for allowance as well under MPEP 608.01(n)(III).

REQUEST FOR ALLOWANCE

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,

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